

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER  
19-815/S-005**

**Chemistry Review(s)**

<b>CHEMIST'S REVIEW</b>		<b>1. ORGANIZATION</b> HFD - 110	<b>2. NDA Number</b> 19-815
<b>3. Name and Address of Applicant (City &amp; State)</b>  Shire Laboratories, Inc. 1550 East Gude Drive Rockville, MD 20850		<b>4. Supplement(s) Number(s)</b>  <b>Date(s)</b>	
<b>5. Drug Name</b>  ProAmatine	<b>6. Nonproprietary Name</b>  Midodrine Hydrochloride		<b>8. Amendments &amp; Other (reports, etc)</b>  SCM-005 (BL) <b>Date(s)</b>  11-20-01  03-14-02
<b>7. Amendment Provides For:</b>  Reply to Agency's Approvable Letter of August 31, 2001 regarding ProAmatine Tablet 10 mg as an additional strength to the existing 2.5 mg and 5.0 mg strengths.			
<b>9. Pharmacological Category</b>  Vasopressor	<b>10. How Dispensed</b>  <u>/x</u> / RX <u>  </u> / OTC		<b>11. Related IND(s)/ NDA(s)/DMF(s)</b>
<b>12. Dosage Form(s)</b>  Tablet	<b>13. Potency(ies)</b> 2.5, 5 and 10 mg		
<b>14. Chemical Name</b>  Acetamide, 2-amino-N-2 [2- (2,5-dimethoxyphenyl) -2-hydroxyethyl]-, mono-hydrochloride, ( ± )			<b>15. Records/Reports Current</b>  <u>/x</u> / Yes <u>  </u> / No  Reviewed  <u>/x</u> / Yes <u>  </u> / No
<b>16. Comments:</b>  See review notes.			
<b>17. Conclusions and Recommendations:</b>  All the deficiencies have been satisfactory addressed and supplement is approved.			
<b>18. REVIEWER Name</b>  Ramsharan D. Mittal			<b>Date Completed</b> 03/20/02

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/s/

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3/20/02 04:31:27 PM  
CHEMIST

Kasturi Srinivasachar  
3/20/02 05:00:48 PM  
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